Can a self-reported questionnaire replace interview assessments for detection of late radiation sequelae in prostate cancer patients treated by radical irradiation?

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Prostate cancer, Irradiation, Late normal tissue reactions, SOMA score

Abstract

The prevalence of long term survivors after cancer treatment is increasing and a large number of patients are at risk for development of treatment-related sequelae. With limitation of health care resources, low cost methods are needed to screen this population for sequelae.

A total of 255 prostate cancer patients treated with curative radiotherapy at one institution was identified and responses to self-reported questionnaires based on Soma score for rectal and urinary symptoms were analyzed and compared with a similar questionnaires filled in by an experienced study nurse during patient interview.

Results: 65% of living patients returned the questionnaires and 51% showed up for the interview. The median follow up time after irradiation was 6,9 years. 57% of the patients scored the same as the nurse in an interview setting, while 35% scored higher in the self reported forms than in the interview scores. Overall, the self-reported questionnaire identified 97% of patients with scores $\geq$2 at interview.

Conclusion: Self reported questionnaires may be a low cost method to help screen populations at risk for treatment related sequelae after prostate irradiation.

Introduction

Fortunately, there are an increasing number of patients that are long term survivors after cancer therapy [1]. A prevalence of 3,9% of the total population in Norway has been reported in 2008 and similar figures have been reported from other countries in the western world including USA. Radiotherapy is a major cancer treatment modality. However, curative radiotherapy is often given with dose-fractionation schedules that may result in normal tissue damage. Normal tissue injury may thus be the main limiting factor for the curative potential of radiotherapy in local or locally advanced neoplasms and these patients are at risk for development of radiation sequelae.

In times with limitation of resources, follow up by specialists may be of short duration and treatment related sequelae may remain partly undetected as late normal tissue reactions may take a long time to develop. There is thus a need for low cost methods that can detect these sequelae and thus ensure that the patients can get the help needed as well as ensure optimal quality of the cancer care provided. Completion of questionnaires assessing long-term effects may provide a cost-effective method to identify patients with adverse reactions in need of medical help. We tested this hypothesis in a sample of long term survivors after prostate radiotherapy.

Patients and Methods

During the 14 year period from 1984 to 1998 a total of 314 prostate cancer patients were irradiated with curative intent at Ullevaal University Hospital in Norway and 255 patients were alive at time for follow up and included in the present study. The majority of the patients were treated after 1991. This was generally at a time before neoadjuvant and adjuvant hormonal treatment had been implemented and all these patients were treated with 70,00 Gy given with 2,00 Gy daily fractions. Generally, a three-dimensional conformal CT plan was used and the irradiation technique involving three fields where one field was administered from the front and two oblique fields from posterior with the patients in prone position. Only a few patients (39) underwent lymph node staging before irradiation. For planning, the internal margin and set up margin was set to 1,5 cm in accordance with treatment protocol SPCG VII developed by SPCG (Scandinavian Prostate Cancer Group).

According to a modified D' Amico risk group classification, 83% of the patients could be classified as high risk (T3 or PSA> 20 or WHO grade 3), 16% were at intermediate risk (T2 or PSA 10-20 or WHO grade 2): and only 1% were categorized as low risk (T1, PSA <10 and WHO grade 1) [2]. The median age at radiotherapy was 67 years (64-70 as 25^{th} and 75^{th} percentiles) and the median PSA was 22,5 μg/L (11,5-41,6 μg/L).

The median follow up time from radiotherapy was 6,9 years and the cumulative follow-up time was 2084 patient-years. Urinary and rectal normal tissue reactions were assessed by SOMA scores [3-4,], appendix 1 and 2. The patients were first contacted by mail and invited to fill in a questionnaire with the symptomatic scores for urinary and rectal complications based on the SOMA scale, translated to Norwegian [5], appendix 3. Pre-stamped envelopes for return mail were supplied The answers were optically read and

computed into a Microsoft Access database. Along with the questionnaire the patients were asked if they would like to come for a consultation, which took place approx 4 months later. At consultation, the patients were assessed by the same experienced research nurse and rectal and urinary symptomatic scores were again recorded.

Statistical methods

Descriptive data are presented as median values with 25^{th} and 75^{th} percentiles (25p, 75p) or proportions. To compare self-reported scores and interview scores we computed proportions of pairs for which clinicians and patients gave an identical score or diverged. Spearmann rank correlation coefficient was used to detect concordance between self-reported scores and interview scores. We also dichotomised symptom scores into ≥2 and ≥3 categories. Sensitivity and specificity were computed for symptom scores ≥2 using interview scores as a gold standard. Further, the Chi-square test detected associations between categorical independent variables. All p-values are two-sided, and a 5% significance level was used. Statistical analysis was performed using SPSS for Windows, version 15 (SPSS Inc., Chicago, IL, USA).

Results

A total of 165 patients i.e. 65% returned a completed questionnaire by mail and 151 patients replied that they wanted to come for a consultation but only a total of 130 patients i.e. 51% of patients alive showed up for consultation.

In the self-reported questionnaires a total of 61% reported toxicity with grade $\geq$ 2 from the bladder/urethra and 66% from the rectum. Grade $\geq$ 3 bladder/urethra and rectum toxicity was reported as 25% and 12,5% respectively. In the interview setting comparable figures were lower with only 48% graded as toxicity grade $\geq$ 2 from the bladder/urethra

and 32,8% from rectum. Only 16% toxicity grade $\geq$ 3 were detected for both bladder/urethra and rectum.

The frequencies of toxicity scores detected are shown in Table 1 where the self-reported scores are shown in black and the scores at interview are shown in red.

To illustrate the agreement or disagreement between patients and clinician, Figure 1 depicts columns of different scores of each side effects where patients or clinicians scored higher than each other as well as where they scored equally. [6].

The self-reported questionnaire detected 97% of patients with scores $\geq$2 at consultation and 86% with scores $\geq$3. The sensitivity is 95% (95% CI: 87 - 98) for detection of scores $\geq$ 2 on the self-reported questionnaire compared to scores at consultation while specificity was only 35% (95% CI: 23-48).

Discussion

The SOMA-score was developed to perform intra- and inter trials comparisons of normal tissue toxicity after radiation therapy. The SOMA score involves both a **s**ubjective, **o**bjective, **m**edical management and **a**nalytic part [7]. We have only used the subjective part in our study, as this is the only part that can be used in a self-reported questionnaire. However, caution must be advised as the Soma scores were developed for use in an interview setting and not as a patient self-reported questionnaire. There was, on the other hand, a relatively good concordance between what the patients reported on the questionnaire and in the interview setting.

In this study composite LENT (Late effects normal tissue) scores are not used in agreement with Juliana Denekamp that promoted that individual scores must be compared and sums and divisions of scores may be misleading [8]. Similarly, it is hard to compare scores of different normal tissue effects graded equally. For example, it is not given that hourly urinary frequency that is graded as 4 equals refractory incontinence that has the same grade. It will be easier for the patient and doctor to decide on a treatment modality if it is possible to assess the risk of normal tissue toxicity when each symptom can be evaluated separately rather than in groups of severity. Another problem with the subjective SOMA score is that it does not separate mucus from bleeding from the rectum as bleeding is part of the objective parameters. For this reason, many still use the RTOG/EORTC toxicity scores [9].

The response rate to the mailed questionnaire was satisfactory as 65% replied and the surviving patient population was quite old at that time. (Those who did not reply had a median age of 75 years and we did not have information whether a large proportion of these patients may be disabled from other causes or institutionalized etc.). Of those who replied, 79% showed up for consultation and many expressed gratitude for being followed up.

With a median follow-up time of 6,9 years in this study most late radiation effects should have been manifested. And even though there are reports that late radiation sequelae may fade with time, [10,11] the 4 months interval between the filling of the self reported questionnaire and the interview should have little impact on the results.

The toxicity results scored by clinician in our series can be compared to that of other studies [11]. Grade 3 and 4 urinary toxicity were rare, both reported by patient and interviewer. The most frequent urinary grade 2 toxicity reported by the patients was 25,9% for urinary frequency and during interview 19,5%. Decreased stream, which was self-reported in 20,6% of patients and by clinician 26,6% of patients. However, we had no registration of scores prior to treatment and corrections for the natural development in the normal population was not done. Our results can thus only tell something about the patients' subjective complaints at the time of assessment and can not directly be related to the therapy. Grade 3 and 4 rectal toxicity was rare. The only grade 4 reported was for sphincter control. The most frequent grade 2 score were mucus discharge or bleeding, 41,0% and 4,7%, reported by the patients and interviewer, respectively. This large discrepancy between the self-reported and interview reported scores may be due to interpretation error by the patient as mucosal loss probably needs a better description in a patient questionnaire than what we used.

The agreement between the patients and interviewer was however generally good. For the different symptoms, the range for which the interviewer and patient scored the same grade was from 37,5% to 86,2%, the average being 56,5%. Where there was a disagreement in the grade, the patients generally scored higher than the interviewer for all symptoms. This phenomenon has also been reported by others and will be discussed below. The highest difference was for mucus and bleeding from rectum, where 36,5% of the patients evaluated the symptoms to be two grades or higher symptom score than the interviewer did. Overall 58% reported higher in the self-assessment than the interview

setting for this symptom score. While mucus may be a quite innocent symptom, bleeding from the rectum may have severe consequences. However, bleeding may be from haemorrhoids and may not be due to radiation proctitis. The symptom registration of bleeding as a screening procedure may be useful even though the sensitivity is high and specificity is low. Rectal bleeding has also been used as an endpoint in several other studies, especially in studies of dose-volume constraints [12].

The systematic approach with specific list of symptom questions may reveal a larger number of symptoms than the patients would report spontaneously [13]. The use of questionnaires mentioning multiple possible symptoms may record symptoms more effectively than interviewing the patients [7]. There may, however, be many pitfalls in interpreting patients versus clinician's reports of symptoms. But, generally, patient symptom reporting may add to the symptom monitoring and may provide a low cost useful tool for screening for sequelae. In our series we found that patients assigned greater severity to symptoms than the clinician. This is also in accordance with other studies using other questionnaires. Most studies found that the patients reported more symptoms and greater severity of symptoms, or that the patients and interviewers reported symptoms had high agreement, and that when there was a difference the patient usually reported more symptoms. We failed to find any studies were the clinicians report more symptoms than the patients.

In two different studies regarding symptoms in patients with gynaecological cancer, there was a high agreement between the symptoms the patients reported using a questionnaire and the observer reported symptoms [14,15].

Comparing doctors and patients reports of symptoms after prostate irradiation, Lilleby et al found that the patient usually reported more symptoms [16]. Watkins-Bruner et al found that medical professionals underreported symptoms compared to when self-reported by the patient using quality of life instruments after radiation therapy for prostate cancer [17]. Litwin et al have compared urologists' assessment of symptoms to patients' in patients with prostate cancer, and found that the urologists underestimated the symptoms [18]. Similarly, after radiotherapy the clinicians underreported the severity of symptoms compared to patients answering a questionnaire, in patients with cancer in the oral cavity, larynx and pharynx. The conclusion was that patient's selfreport of symptoms is a more sensitive method for evaluating side effects than clinicians evaluation [19]. Meirovitz et al compared the grading of xerostomia severity after radiotherapy by the patients themselves, clinicians and to measurement of a major salivary gland flow. They found a correlation between the symptoms patients reported themselves and the salivary gland flow, but no significant correlation between the observer grading and the salivary gland flow measurement or the patient self-report of symptoms. The clinicians underestimated the severity of xerostomia [20]. Bjordal et al also found that found that the patient reported more symptoms and a lower quality of life than the clinician did after cancer treatment [21]. A study comparing symptoms after chemotherapy reported by the patient using a questionnaire with physicians' reported symptoms, found that the patients' reports were more sensitive and thus better suited for the investigation of symptoms [22]. Vistad et al found that physicians underreport symptoms after radiotherapy for cervical cancer [23]. Other studies have found that patients and the interviewer report similar amount and degree of symptoms. Basch et al compared side effects reported by the

patient and clinician in lung and genitourinary cancer clinics. They found that the agreement between the groups was high. Were there was not agreement patients reported more severe symptoms. These results can be compared to what we found in our study. Basch et al also found that difference between the groups rarely was sufficient enough that it would have any effect on deciding whether to start treatment of the symptoms or not [6].

Clinicians may have a tendency to underestimate symptom severity, and others have indicated that this may have important implications for interventions [24].

The above-mentioned studies are all in concordance with our findings. However these studies used different methods and questionnaires. In our study, the same questionnaire (only with slight modification) was used by both patients as well as the experienced research nurse. In many studies the patients and clinicians generally used different forms, which can be a source for misinterpretation, although the important factor here is how sensitive the different methods are for discovering the side effects.

The underestimations of symptoms by the interviewer may be unintentionally due to the fact that patients may have a tendency to "please the doctor" and especially men confronted with female health care workers. [25]. This may be part of the explanation why clinicians usually scored lower symptoms than the patients themselves [25,26]. Other reasons might be that the clinicians have a busy schedule and the time spend on each patient is not enough to let the patient come forward with all their symptoms. This may be minimized if one uses self-report questionnaires.

A potential weakness in our study is the fact that the same research nurse did all the interviews. The interviewer may have effect on the results, especially if there are few interviewers, as in our, where there was only one [25]. On the other hand, this may contribute to consistent scoring.

The use of self-reported questionnaire may benefit the patients as sequelae may be detected and possible dealt with, but in addition, important quality indicators of the service may be gathered. The use of self-reported outcomes saves resources compared to ordinary specialist consultations. However, many factors need to be considered in designing the questionnaires for detection of treatment-related sequelae and quality of life. Since the main goal of our study was to evaluate if a self-assessment questionnaire was an effective screening tool for late toxicity after radiotherapy, we did not assess pre-treatment symptoms. Pre-treatment symptoms are an important predictor of post-treatment symptoms, and should therefore be included in trials comparing different treatment modalities [27,11].

As in so many other parts of medicine, other factors that may influence the subjective experience of urinary and rectal morbidities after treatment. Comorbity and even socioeconomic status should also be taken into account when assessing the outcome of treatment [28,29]. The National Urological Cancer Group in Norway (NUCG) has now started a national survey where patient recorded symptoms are registered prospectively and factors as genefactors, age, level of education, personality traits, co-morbidity as well

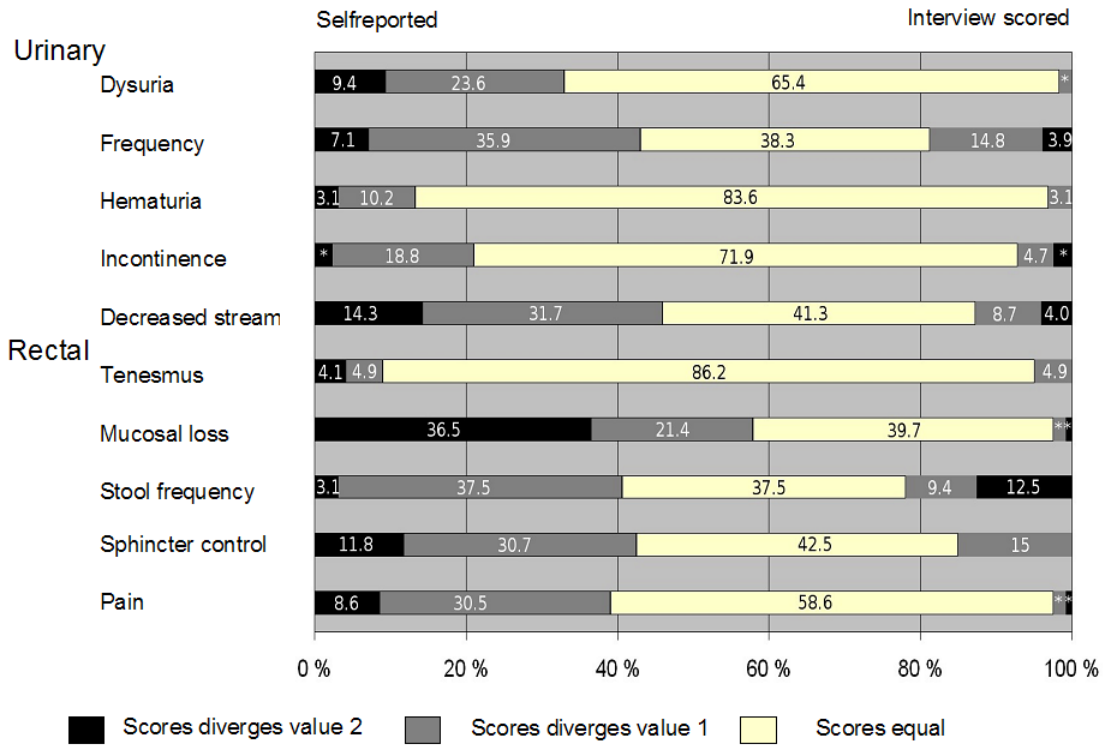
as pre-treatment bowel and bladder function are considered from patients receiving radical therapy for prostate cancer, both surgical- and radiotherapy.

Similarly, patient reported outcomes in cancer care and trials are now advocated [30,31].

Our results indicate that the self-reported questionnaire used was a very sensitive method of detecting toxisity scores $\geq$ 2 compared to scores at consultation. The specificity was however relatively low as the patients generally scored higher on the self-reported forms than clinician during consultation. . But as we have discussed above, it is hard to tell if the clinicians-reported symptom scores are more correct than what the patients scores. It may well be that the patients are more correct.

Conclusion

The use of a self-reported questionnaire with the subjective parameters of urinary and rectal normal tissue reactions in the SOMA scales seems to be sensitive method for low cost screening for late normal tissue sequelae after radiotherapy for prostate cancer as part of a long term follow up strategy.


Selfreported
Interview scored
Urinary
Dysuria
Frequency
Hematuria
Incontinence
Decreased stream
Rectal
Tenesmus
Mucosal loss
Stool frequency
Sphincter control
Pain
9.4
23.6
65.4
*
7.1
35.9
38.3
14.8
3.9
3.1
10.2
83.6
3.1
*
18.8
71.9
4.7
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14.3
31.7
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36.5
21.4
39.7
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3.1
37.5
37.5
9.4
12.5
11.8
30.7
42.5
15
8.6
30.5
58.6
**
0 %
20 %
40 %
60 %
80 %
100 %
Scores diverges value 2
Scores diverges value 1
Scores equal

Fig 1

Table 1 Toxicity scores

	Grade 1	Grade 2	Grade 3	Grade 4
Bladder/Urethra:				
Dysuria	**22,4% (8,6%)**	**11,2% (0)**	**0,6% (0)**	**0,6 (0,8)**
Frequency	**38,9%(30,5%)**	**25,9%(19,5%)**	**9,9%(9,4%)**	**3,7%(0,8%)**
Hematuria	**9,8% (6,3%)**	**5,5%(0,8%)**	**0,6% (0%)**	
Incontinence	**22,4%(14,8%)**	**6,8%(1,6%)**	**1,9% (0)**	**5,6% (5,5%)**
Decreased stream	**29,4%(9,4%)**	**20,6%(26,6%)**	**15,6%(1,6%)**	**0,6% (0,8%)**
Rectum:				
Tenesmus	**6,3% (3,9%)**	**4,4% (1,6%)**	**0,6% (0%)**	
Mocosal loss	**16,8%(10,9%)**	**41,0%(4,7%)**	**3,7% (2,3%)**	
Stool frequency	**55,2%(64,1%)**	**2,5% (4,7%)**	**0,6% (0,8%)**	**4,3% (0%)**
Sphincter control	**23,0%(17,2%)**	**39,8% (7,8%)**	**3,7% (10,9%)**	
Pain	**28,2% (7,0%)**	**11,0%(3,1%)**	**1,2% (0,8%)**	

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BLADDER/URETHRA

Pasientnummer: ☐☐☐

	GRADE 1	GRADE 2	GRADE 3	GRADE 4	
Subjective					
Dysuria	☐ Occasional & minimal	☐ Intermittent & tolerable	☐ Persistant & intense	☐ Refractory & excruciating	☐
Frequency	☐ 3-4 hour intervals	☐ 2-3 hour intervals	☐ 1-2 hour intervals	☐ Hourly	☐
Hematuria	☐ Occasional	☐ Intermittent	☐ Persistent with clot	☐ Refractory	☐
Incontinence	☐ < weekly episodes	☐ < daily episodes	☐ ≤ 2pads/undergarment /day	☐ Refractory	☐
Decreased stream	☐ Occasionally weak	☐ Intermittent	☐ Persistant but in complete obstruction	☐ Complete obstruction	☐
Objectiv					
Hematuria	☐ Microscopic, normal hemoglobin	☐ Intermittent macroscopic, <10% decrease in hemoglobin	☐ Persistant macroscopic, 10%-20% decrease in hemoglobin	☐ Refractory, >20% decrease in hemoglobin	☐
Endoscopy	☐ Patchy, atrophy or Telangiectasia without bleeding	☐ Confluent atrophy or Telangiectasia with gross bleeding	☐ Ulcerations into muscle	☐ Perforation, fistula	☐
Maximum volume	☐ >300cc - 400cc	☐ >200cc - 300cc	☐ >100cc - 200cc	☐ ≤100cc	☐
Residual volume	☐ 25cc	☐ >25cc - 100cc	☐ >100cc	☐	☐
Management					
Dysuria	☐ Occasional non-narcotic	☐ Regular non-narcotic	☐ Regular narcotic	☐ Surgical intervention	☐
Frequency	☐ Alkalization	☐ Occasional anti-spasmodic	☐ Regular narcotic	☐ Cystectomy	☐
Hematuria/ Telangiectasia	☐ Iron therapy	☐ Occasional transfusion or single cauterization	☐ Frequent transfusion or coagulation	☐ Surgical intervention	☐
Incontinence	☐ Occasional use of incontinence pads	☐ Intermittent use of incontinence pads	☐ Regular use of pads or selfcatheterization	☐ Permanent catheter	☐
Decreased stream	☐	☐ <Once-a-day self-catheterization	☐ Dilatation, >once-a-day self -catheterization	☐ Permanent catheter, surgical intervention	☐

SCORING Instructions

Score the 14 SOM parameters with 1-4

(Score = 0 if there are no toxicities)

Total the scores and divide by 14

LENT Score: ☐☐

Analytic				Date
Cystography	Assessment of mucosal surface	☐ Yes	☐ No	☐☐.☐☐.☐☐
Volumetric analysis	Assessment of bladder capacity in milliliters	☐ Yes	☐ No	☐☐.☐☐.☐☐
Contrast radiography	Assessment for ulcers, capacity and contractility	☐ Yes	☐ No	☐☐.☐☐.☐☐
Ultrasound	Assessment of wall thickness, sinus and fistula formation	☐ Yes	☐ No	☐☐.☐☐.☐☐
Electro-myography	Assessment of sphincter activity using intralumenal pressure transducer, contraction pressure and volume curves	☐ Yes	☐ No	☐☐.☐☐.☐☐

Appendix1

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RECTUM

Pasientnummer: ☐☐☐

	GRADE 1	GRADE 2	GRADE 3	GRADE 4	
Subjective					
Tenesmus	☐ Occasional urgency	☐ Intermittent urgency	☐ Persistant urgency	☐ Refractory	☐
Mucosal,loss	☐ Occasional	☐ Intermittent	☐ Persistent	☐ Refractory	☐
Sphincter control	☐ Occasional	☐ Intermittent	☐ Persistent	☐ Refractory	☐
Stool frequency	☐ 2-4 per day	☐ 4-8 per day	☐ >8 per day	☐ Uncontrolled diarrhea	☐
Pain	☐ Occasional & minimal	☐ Intermittent & tolerable	☐ Persistant & intense	☐ Refractory & excruciating	☐
Objectiv					
Bleeding	☐ Occult	☐ Occasionally >2/week	☐ Persistant/daily	☐ Gross hemorrhage	☐
Ulceration	☐ Superficial $\leq 1cm^2$	☐ Superficial $>1cm^2$	☐ Deep ulcer	☐ Perforation, Fistulae	☐
Stricture	☐ >300cc - 400cc	☐ >200cc - 300cc	☐ >100cc - 200cc	☐ $\leq$100cc	☐
Management					
Tenesmus & stool frequency	☐ Occasional $\leq$2 anti-diarrheals/week	☐ Regular >2 anti-diarrheals/week	☐ Multiple >2 anti-diarrheals/day	☐ Surgical intervention Permanent/colostomy	☐
Pain	☐ Occasional non-narcotic	☐ Regular non-narcotic	☐ Regular narcotic	☐ Surgical intervention	☐
Bleeding	☐ Stool softener, iron therapy	☐ Occasional transfusion	☐ Frequent transfusions	☐ Surgical intervention Permanent/colostomy	☐
Ulceration	☐ Diet modification, stool softener	☐ Occasional steroids	☐ Steroids per enema, hyperbaric oxygen	☐ Surgical intervention Permanent/colostomy	☐
Stricture	☐ Diet modification	☐ Occasional dilatation	☐ Regular dilatation	☐ Surgical intervention Permanent/colostomy	☐
Sphincter control	☐ Occasional use of incontinence pads	☐ Intermittent use of incontinence pads	☐ Persistant use of incontinence pads	☐ Surgical intervention Permanent/colostomy	☐

SCORING
Instructions

Score the 14 SOM parameters with 1-4

(Score = 0 if there are no toxicities)

Total the scores and divide by 11

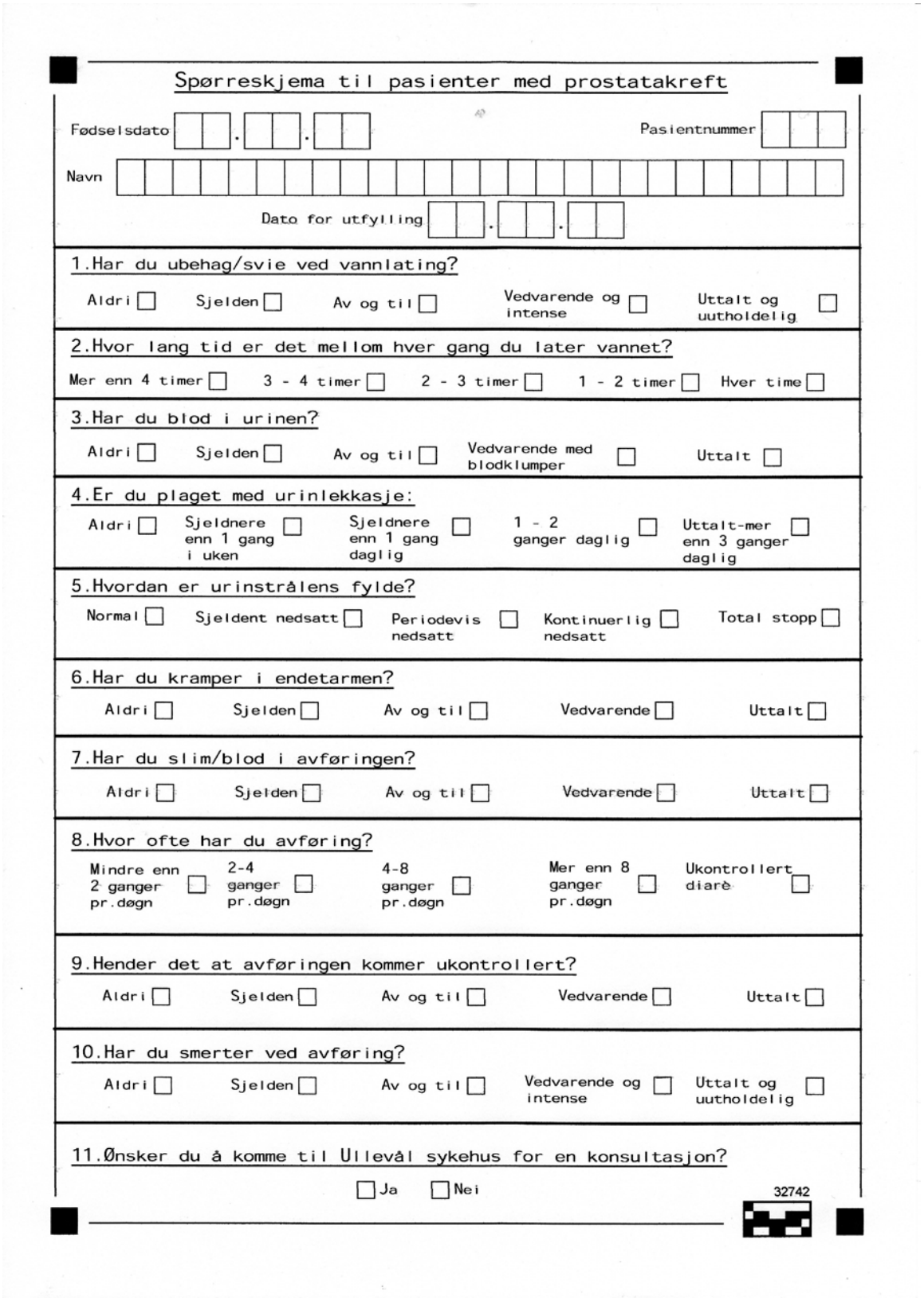
LENT Score: ☐☐

Analytic				Date
Barium enema	Assessment of lumen and peristalsis	☐ Yes	☐ No	☐☐.☐☐.☐☐
Proctoscopy	Assessment of lumen and mucosal surface	☐ Yes	☐ No	☐☐.☐☐.☐☐
CT	Assessment of wall thickness, sinus and fistula formation	☐ Yes	☐ No	☐☐.☐☐.☐☐
MRI	Assessment of wall thickness, sinus and fistula formation	☐ Yes	☐ No	☐☐.☐☐.☐☐
Anal manometry	Assessment rectal compliance	☐ Yes	☐ No	☐☐.☐☐.☐☐
Ultrasound	Assessment of wall thickness, sinus and fistula formation	☐ Yes	☐ No	☐☐.☐☐.☐☐

PSA: ☐☐☐☐,☐

Appendix2

Appendix3



Spørreskjema til pasienter med prostatakreft

Fødselsdato ☐☐.☐☐.☐☐ Pasientnummer ☐☐☐

Navn ☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐☐

Dato for utfylling ☐☐.☐☐.☐☐

1. Har du ubehag/svie ved vannlating?

Aldri ☐ Sjelden ☐ Av og til ☐ Vedvarende og intense ☐ Uttalt og uutholdelig ☐

2. Hvor lang tid er det mellom hver gang du later vannet?

Mer enn 4 timer ☐ 3 - 4 timer ☐ 2 - 3 timer ☐ 1 - 2 timer ☐ Hver time ☐

3. Har du blod i urinen?

Aldri ☐ Sjelden ☐ Av og til ☐ Vedvarende med blodklumper ☐ Uttalt ☐

4. Er du plaget med urinlekkasje:

Aldri ☐ Sjeldnere enn 1 gang i uken ☐ Sjeldnere enn 1 gang daglig ☐ 1 - 2 ganger daglig ☐ Uttalt-mer enn 3 ganger daglig ☐

5. Hvordan er urinstrålens fylde?

Normal ☐ Sjeldent nedsatt ☐ Periodevis nedsatt ☐ Kontinuerlig nedsatt ☐ Total stopp ☐

6. Har du kramper i endetarmen?

Aldri ☐ Sjelden ☐ Av og til ☐ Vedvarende ☐ Uttalt ☐

7. Har du slim/blod i avføringen?

Aldri ☐ Sjelden ☐ Av og til ☐ Vedvarende ☐ Uttalt ☐

8. Hvor ofte har du avføring?

Mindre enn 2 ganger pr.døgn ☐ 2-4 ganger pr.døgn ☐ 4-8 ganger pr.døgn ☐ Mer enn 8 ganger pr.døgn ☐ Ukontrollert diarè ☐

9. Hender det at avføringen kommer ukontrollert?

Aldri ☐ Sjelden ☐ Av og til ☐ Vedvarende ☐ Uttalt ☐

10. Har du smerter ved avføring?

Aldri ☐ Sjelden ☐ Av og til ☐ Vedvarende og intense ☐ Uttalt og uutholdelig ☐

11. Ønsker du å komme til Ullevål sykehus for en konsultasjon?

☐ Ja ☐ Nei

32742

Legends

Figure 1: Agreement or disagreement between self-assessment and clinician in toxicity. Self-assessment scores higher and interview scores higher, left and right respectively. In the middle the scores are the same for both self-assessment and interview.. * denotes score less than 3,0%.

Table 1: Self-reported subjective toxicity scores are shown in black and scores at interview are shown in red.

This study was approved by regional ethics comity.

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References:

[1]: Cancer in Norway 2007, www. Kreftregisteret.no.

[2]: D'Amico AV, Moul J, Carell PR, Sun L, Lubeck D, Chen M-H. Cancer-specific mortality after surgery or radiation for patients with clinically localized prostate cancer managed during the prostate-specific antigen era. J.Clin Oncol 2003; 21: 2163-2172.

[3]: Coia LR, Myerson RJ, Tepper JE. Late effects of radiation therapy on the gastrointestinal tract. Int J Radiat Oncol. Biol Phys 1995; 31: 1213-1236.

[4]: Marks LB, Carroll PR, Dugan TC, Anscher MS.. The response of the urinary bladder, urethra and ureter to radiation and chemotherapy. Int J Radiat Oncol Biol Phys. 1995; 31: 1257-1280.

[5]: Bakken A-M, Øgreid P, Iversen J. Langberg CW. Normalvevstoksisitet ved strålebehandling av lokalisert protatakreft. Tidsskr Nor Lægeforen 1999; 14: 2017-21.

[6]: Basch E, Iasonos A, McDonough T, Barz A, Culkin A, Kris MG, et al. Patient versus clinician symptom reporting using the National Cancer Institute Common Terminology Criteria for Adverse Events: results of a questionnaire-based study. Lancet Oncol 2006; 7: 903-09.

[7]: Pavy JJ, Denekamp J, Letschert J, Littbrand B, Mornex F, Bernier J et al. EORTC Late Effects Working Group. Late effects toxicity scoring: the SOMA scale. Radiother Oncol 1995; 35: 11-15.

[8]: Denekamp J, Bartelink H, Rubin P. Correction for the use of the SOMA LENT tables. American and European LENT Working Committees. Radiother Oncol 1996; 39(2): 191.

[9]: Cox D, Stetz J, Pajak TF. Toxicity criteria of the Radiation Therapy Oncology Group (RTOG) and the European Organization for Research and Treatment of Cancer (EORTC). Int J Radiat Oncol Biol Phys 1995; 31: 1341-46.

[10]: Christie D, Denham J, Steigler A, Lamb D, Turner S, Mameghan H, et al. Delayed rectal and urinary symptomatology in patients treated for prostate cancer by radiotherapy with or without short term neo-adjuvant androgen deprivation. Radiother Oncol. 2005;77:117-125.

[11]: Karlsdottir A, Muren LP, Wentzel-Larsen T, Dahl O. Late gastrointestinal morbidity after three dimensional conformal radiation therapy for prostate cancer fades with time in contrast to genitourinary morbidity. Int J Radiat Oncol Biol Phys. 2008; 70: 1478-1486.

[12]: Chan LW, Xia P, Gottschalk AR, Akazawa M, Scala M, Pickett B, et al. Proposed rectal dose constraints for patients undergoing definitive whole pelvic radiation therapy for clinically localized prostate cancer. Int J Radiat Oncol Biol Phys 2008; 72: 1-9.

[13]: Homsi J, Walsh D, Rivera N, Rybicki LA, Nelson KA, Legrand SB, et al. Symptom evaluation in palliative medicine: patient report vs systematic assessment. Support Care Cancer 2006; 14: 444-453.

[14]: Jensen PT, Klee MC, Thranov I, Groenvold M. Validation of a questionnaire for self-assessment of sexual function and vaginal changes after gynaecological cancer. Psychooncology. 2004; 13(8): 577-92.

[15]: Jensen PT, Klee MC, Groenvald M. Validation of a questionnaire for self-rating of urological and gynaecological morbidity after treatment of gynaecological cancer. Radiother Oncol. 2002; 65(1): 29-38.

[16]: Lilleby W, Fosså SD, Waehre HR, Olsen DR. Long-term mobidity and quality of life in patients with localized prostate cancer undergoing definitive radiotherapy or radical prostatectomy Int. J. Radiation Oncology Biol. Phys. 1999; 43: 735-743.
[17]: Watkins-Bruner D, Scott C, Lawton C, DelRowe J, Rotman M, Buswell L, et al. RTOG's first quality of life study--RTOG 90-20: a phase II trial of external beam radiation with etanidazole for locally advanced prostate cancer. Int J Radiat Oncol Biol Phys. 1995; 33(4): 901-6.
[18]: Litwin MS, Lubeck DP, Henning JM, Carroll PR. Differences in urologist and patient assessments of health related quality of life in men with prostate cancer: results of the CaPSURE database. J Urol. 1998; 159(6): 1988-92.
[19]: Jensen K, Bonde Jensen A, Grau C. The relationship between observer-based toxicity scoring and patient assessed symptom severity after treatment for head and neck cancer. A correlative cross sectional study of the DAHANCA toxicity scoring system and the EORTC quality of life questionnaires. Radiother Oncol. 2006; 78(3): 298-305.
[20]: Meirovitz A, Murdoch-Kinch CA, Schipper M, Pan C, Eisbruch A. Grading xerostomia by physicians or by patients after intensity-modulated radiotherapy of head-and-neck cancer. Int J Radiat Oncol Biol Phys. 2006; 66(2): 445-53.
[21]: Bjordal K, Freng A, Thorvik J, Kaasa S. Patient self-reported and clinician-rated quality of life in head and neck cancer patients: a cross-sectional study. Eur J Cancer B Oral Oncol. 1995; 31B(4): 235-41.
[22]: Fromme EK, Eilers KM, Mori M, Hsieh YC, Beer TM. How accurate is clinician reporting of chemotherapy adverse effects? A comparison with patient-reported

symptoms from the Quality-of-Life Questionnaire C30. J Clin Oncol. 2004; 22(17): 3485-90.

[23]: Vistad I, Cvancarova M, Fosså SD, Kristensen GB. Post-radiotherapy morbidity in long term survivors after locally advanced cervical cancer. How well do physicians' assessments agree with those of the patients? Int J Radiat Oncol Biol Phys. 2008; 71: 1335-42.

[24]: Stephens RJ, Hopwood P, Girling DJ, Machin D. Radomized trials with quality of life endpoints: Are doctors' rating of patients' physical symptoms interchangeable with patients' self-ratings? Quality of Life Res. 1997; 6: 225-236.

[25] Moum T. Mode of administration and interviewer effects in self-reported symptoms of anxiety and depression. Social Indicators Research. 1998; 45: 279-318.

[26] Aslaksen PM, Myrbakk IN, Høifødt RS, Flaten MA. The effect of experimenter gender on autonomic and subjective response to pain stimuli. Pain 2007; 129: 260-8.

[27]: Talcott JA, Manola J, Clark JA, Kaplan I, Beard CJ, Mitchell SP, et al. Time course and predictors of symptoms after primary prostate cancer therapy. Journal of Clinical Oncology 2003; 21: 3979-3986.

[28]: Karakiewicz PI, Bhojani N, Neugut A, Shariat SF, Jeldres C, Graefen M, et al. The effect of comorbidity and socioeconomic status on sexual and urinary function and on general health-related quality of life in men treated with radical prostatectomy for localized prostate cancer. J Sex Med. 2008; 5(4): 919-27.

[29]: Gudbergsson SB, Fosså SD, Ganz PA, Zebrack BJ, Dahl AA. The associations between living conditions, demography, and the impact of cancer scale in tumor-freee cancer survivors: a NOCWO study. Support Care Cancer. 2007; 15: 1309-1318.

[30]: Revicki DA, Erickson PA, Sloan JA, Dueck A, Guess H, Santanello NC, et al. Interpreting and reporting results based on patient reported outcomes. Value Health 2007; 10: S116-24.

[31]: Sloan JA, Berk L, Roscoe J, Fisch MJ, Shaw EG, Wyatt G,et al. Integrating patient-reported outcomes into cancer symptom management trial supported by the National cancer institute- sponsored clinical trials network. J Clin Oncol. 2007; 32: 5070-5077.